

Appln No. 10/687,847

Amdt late April 11, 2005

Reply to Office action of January 11, 2005

Amendments to the Drawings:

The attached sheet of drawing includes a change to FIG. 3. This sheet, which includes Figs. 3-4, replaces the original sheet including Fig. 3-4.

Attachment: Replacement Sheet
 Annotated Sheet Showing Changes

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REMARKS/ARGUMENTS

Claims 1-39 are pending in the above-referenced application. Claims 1, 10, and 26 have been amended to further define Applicant's invention, none of which were made in response to the instant Office Action.

This is a response to the Office Action dated January 11, 2005 wherein the Examiner rejected pending claims 1-39. In particular, claims 1, 7-8, and 36 are rejected under 35 U.S.C. 102(b) for being anticipated by Sand et al. US 6,655,401; and the following claims rejected under 35 U.S.C. 103(a) for obviousness: claims 26 and 31-32 by Sand et al. in view of common knowledge in the art; claims 2-3, 5-6, 9-13, 15-19, 21-25, 27-30, and 37-39 by Sand et al. in view of Wachman et al. (USP 5,424,323); claims 4, 14, and 20 by Sand in view of Wachman and Dalhart et al. (USP 6,619,318); and claims 33-35 by Sand in view of Wachman and Stanley (Pub. No. 2004/0156744). Please reconsider in view of the remarks that follow.

The Examiner also objected to the specification for two informalities: (1) in paragraph [0028], element "20" was used twice to designate an eductor and a valve, and (2) in paragraph [0029], element reference number "83" should instead be "86", corresponding to "86" in FIG. 3. In response thereto, Applicant has amended paragraphs [0028] and [0029] and FIG. 3 as indicated above to correct the informalities. Notice and entry thereof are respectfully requested.

§102(b) Rejection of Claims 1, 7-8, and 36 by Sand et al.

The Examiner contends claims 1, 7-8 and 36 are anticipated by Sand et al. and referred to several text sections of the '401 patent to support his position. However, Sand et al. do not disclose each and every element of claims 1, 7-8, and 36 as required under §102(b), the rejection is traversed.

Preliminarily, for a reference to anticipate a claimed invention under 35 U.S.C. §102(b), it must adequately meet the terms of the claimed invention interpreted in light of the specification of the application. As set forth in the statute, the single prior art reference must disclose each and every element of the claim under consideration. Moreover, it cannot be rebuilt

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or reoriented by the utilization of Applicant's teachings in an attempt to create an anticipatory structure. As further discussed below, Applicant submits that Sand et al. fail to anticipate the rejected claims by disclosing each and every element thereof.

Claim 1 recites a method for diluting a concentrated solution of sterilant for sterilizing instruments or equipment comprising the steps: providing an eductor, the eductor comprising a metering tip having a first orifice size, a chemical inlet port, and a water inlet port; hooking a container containing concentrated sterilant to the chemical inlet port of the eductor; hooking a water supply source to the water inlet port of the eductor, the water supply source comprising a regulating valve for regulating a working pressure of the water supply; activating the eductor to mix water and concentrated sterilant to a desired admixture containing a volume of sterilant to a volume of water; adjusting the admixture by varying the volume of the sterilant to the volume of water by varying at least one of the metering tip to one having a second orifice size and the working pressure of the water supply to the eductor; and using the admixture to sterilize an instrument for use in treating a subject.

Applicant submits that while eductors are well known in the art for producing an admixture of the two or more products, or for diluting a concentrated product, the mechanism for mixing a specified blend of two or more products is generally limited to changing the orifice size of a metering tip to produce a desired ratio. Prior art devices typically involve a system whereby a water pressure source is connected to an eductor and one or more concentrated solution also connected to the eductor. The water pressure source is operatively controlled by a block valve. When the block valve is opened, a stream of water passes over the eductor and creates a lower pressure region, which is used to draw up the concentrated solution to produce an admixture.

Referring now to the Sand et al. reference, the '401 Sand et al. patent is considered the primary reference in the instant Office Action. Thus, if the claims can be shown to distinguish from Sand et al. and no other reference cited to make up for the deficiencies of Sand et al., then the rejections under § 102(b) and § 103(a) must be rescinded.

The Sand et al. reference is directed to a dispenser capable of selectively mixing one or more than one (up to four) concentrated solutions to produce a single admixture of diluted

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solution. Sand et al. disclose four embodiments: FIGs. 4-5 (first embodiment), FIGs. 6-8 (second embodiment), FIGs. 9-10 (third embodiment), and FIGs. 11-12 (four embodiment). Broadly speaking, and as further discussed below, Sand et al. disclose an eductor system that uses a metering tip to produce a specified admixture ratio with a supposedly novel concept of incorporating two or more eductors that can be selectively controlled to produce two or more blends of admixture.

In each of the four embodiments, a selector body (62, 122, 162, 210) having an adjustable dial (68, 122, 138, or 142) allows the device to direct motive fluid (pressurized water) through one, two, three, or all four eductors. Each eductor is connected to a concentrated fluid reservoir (e.g., 38 and 40 in FIG. 2), which is connected to the chemical inlet of the eductor having a metering tip ("Typically, a metering tip (not shown) is inserted into the chemical port 94 for controlling the dilution ration of the first chemical fluid, in coordination with the dimensional sizing of the first eductor 88", Col. 4, line 67 to Col. 5, line 3). Depending on the number of eductors selected by the adjustable dial, a corresponding number of chemicals are blended.

The first embodiment (FIGs. 4-5) incorporates a bypass fluid channel 90 (FIG. 5). (See, e.g., Col. 5, lines 15-22) If the adjustable dial is set to bypass, the entire motive fluid will flow through the bypass channel 90 and no chemical will be diluted. The remaining three embodiments do not include this feature.

In all the embodiments, a block valve 34 (FIG. 2) is used to either turn on or turn off the motive fluid (pressurized water) supply ("[i]n some applications, the selection control includes a position wherein no mixed fluids are emitted from the outlet 48, and thus the inlet valve 34 may be omitted or not routinely used." Col. 4, lines 42-45. "The motive fluid is received at an inlet valve 34, depicted as a ball valve. . ." Col. 4, lines 23-24, emphasis added). The valve 34 is not used to regulate water flow or pressure (i.e., to achieve a certain flow rate or line pressure). Instead, the valve is used to simply supply (i.e., turn on or off) the dispenser 30 with pressurized water. Blending ratio is regulated by the metering tip located in each of the four eductors.

Thus, unlike the claimed method, which uses water supply having a regulating valve for regulating the working pressure of the water source supplied to the eductor, the Sand et al. patent

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discloses an eductor system which uses a block valve. Because the block valve does not regulate the working pressure of the supplied water, the eductor systems disclosed by the Sand et al. patent cannot produce an accurate blending ratio of admixture at the outlet as compared to the method employed by claim 1. This position is further supported by the '401 patent disclosure, which states that "in some applications, the selection control includes a position wherein no mixed fluids are emitted from the outlet 48, and thus the inlet valve 34 may be omitted or not routinely used." (Col. 4:42-45). In other words, if a regulating valve is important in regulating an admixture ratio, then it cannot be eliminated. Because Sand et al. disclose that the valve 34 may be omitted, a regulating valve is not used. Blending ratio is instead controlled by metering tip selections.

More information regarding pressure regulating valves can be obtained at the following websites:

<http://www.cashacme.com/pressregvalves.html>

<http://www.sporlan.com/prv.shtm>

<http://www.honeywell.ca/braukmann/products/pdf/d05.pdf>

<http://www.dantevalve.com/pressurereg.html>

<http://www.mcmaster.com> (type "pressure regulating valve" at the "find" box)

More information regarding block valves, such as valve 34 disclosed in the '401 Sand et al. patent, can be obtained at the following websites:

<http://www.pacson.co.uk/>

<http://www.hexvalve.com/block.html>

<http://www.dbb-valves.com/AlcoGroup.htm>

http://tapseis.anl.gov/glossacro/dsp_wordpopup.cfm?word_id=472

Accordingly, as the '401 Sand et al. patent does not disclose each and every element recited by claim 1, Sand et al. cannot anticipate claim 1 as required under §102(b).

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Because claims 7, 8, and 36 depend directly from claim 1, they are allowable over Sand et al. for the same reasons as claim 1. Notice thereof is respectfully requested.

§1(3)(a) Rejection of Claims 26 and 31-32 by Sand et al. in view of Common Knowledge

In rejecting claims 26 and 31-32, the Examiner contends that Sand teaches a method for dispensing an admixture of fluid and water in a proportioning and dispensing unit comprising:

... (b) connecting the water inlet port to a water supply source (motive fluid received at inlet valve 34), said water supply source comprising a pressure regulator having a first water pressure set point (inlet valve 34);

[except that] Sand fails to teach the method comprising the steps of (1) placing a holding container at the outlet port of the eductor for receiving an output stream from the eductor; (2) selecting the first hose comprising unit gradations along at least a portion of the hose length; (3) filling the hose length with a quantity of fluid to a starting fluid level; (4) determining an amount of fluid dispensed from the eductor; (5) determining the percent ratio of fluid dispensed; and (6) adjusting the dilution ratio by changing the metering tip position or water pressure set point if the percent ratio of chemical fluid to water is not as desired.

Despite admitting that Sand et al. do not disclose limitations (1) - (6), the Examiner nonetheless contends that "[i]t would have been obvious to one of ordinary skill in the art at the time the invention was made for a holding container to be placed at the outlet port of the eductor for receiving the output stream of the admixture because Sand teaches that the mixed fluids, e.g., the admixture, are emitted from the device through the outlet and hose connected to the outlet and it would have been obvious that the user would desire to provide a holding container for storing and/or transporting the resulting diluted admixture."

To establish a prima facie case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the

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knowledge generally available to one of ordinary skill in the art to modify the references or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations. MPEP §2143.

Because the Examiner had relied on common knowledge to render so many of the recited limitations, Applicant respectfully traverses the rejection based on violation of, among other things, MPEP §2143 and §2144.03, which sets forth procedures for relying on common knowledge or for taking official notice. MPEP §2144.03 states that "Official notice unsupported by documentary evidence should only be taken by the examiner where the facts asserted to be well-known, or to be common knowledge in the art are capable of instant and unquestionable demonstration as being well-known. Applicant submits that it is not well known in the art to perform several of the recited steps including filling a length of hose comprising a hose length and unit gradation to a starting fluid level and having the option to change a metering tip size or a water pressure set point to a second pressure set point. A reservoir is typically used in the prior art to supply the concentrated solution without concern for unit gradations.

Furthermore, as discussed above with reference to the allowance of claims 1, 7, 8, and 36, Sand et al. do not disclose a pressure regulator having a first water pressure set point but instead only a block valve 34.

Because the Examiner inappropriately relied on common knowledge in violation of MPEP §2143 and §2144.03 and because Sand et al. do not disclose a pressure regulating valve and filling a line to a starting position, the rejection is traversed. Reconsideration and a notice of allowance are respectfully requested.

§103(a) Rejection of Claims 31 and 32 by Sand et al. in view of Common Knowledge

In rejecting claims 31 and 32, which depend directly from independent claim 1, the Examiner contends that Sand et al. disclose aspects of claims 31 and 32 as discussed above with reference to claim 1. The Examiner further contends that the specific limitations set forth in claims 31 and 32 are within common knowledge in the art.

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As support, the Examiner contends that Sand et al. disclose that "in some applications, the section control includes a position where no mixed fluids are emitted from the outlet and thus the inlet valve may be omitted or not routinely used." This statement misquotes or demonstrates the Examiner's miscomprehension of the stated purpose of the valve 34 in relations to the first embodiment (FIGs. 4 and 5). In the '401 patent, as discussed above with reference to the patentability of claim 1, Sand et al. disclose an eductor assembly with a bypass channel or duct 90. When the selector body 62 is rotated to bypass water through the bypass duct 90, no admixture is produced, even though water flows through the eductor assembly. In this instance, according to Sand et al., "the selection control includes a position wherein no mixed fluids are emitted from the outlet 48, and thus the inlet valve 34 may be omitted or not routinely used." In other words, the inlet valve 34 is not required when not producing an admixture if the selector body 62 is rotated to direct water to flow through the bypass channel 90. Hence, the valve 34, contrary to the Examiner's assertion, has nothing to do with adjusting the working pressure to vary the admixture.

Reconsideration and a notice of allowance are respectfully requested.

§103(a) Rejection of Claims 2-3, 5-6, 9-13, 15-19, 21-25, 27-30, and 37-39
by Sand et al. in view of Wachman et al.

In rejecting claims 2-3, 5-6, 9-13, 15-19, 21-25, 27-30, and 37-39, the Examiner relies on Sand et al. in view of Wachman et al. to proffer a prima facie evidence of obviousness.

With respect to claims 2-3, 5-6, and 9, which depend, either directly or indirectly from independent claim 1, the Examiner relied on Sand et al. to disclose as set forth above for the rejection of claim 1 and on Wachman et al. to disclose: (1) mounting the eductor in a health care facility, (2) the concentrated sterilant is a 50% or less by weight solution of glutaraldehyde to water, (3) a sterilant composition that includes a concentrated sterilant, water, and a diluent, such as a pH adjusting agent; (4) a pressure gauge mounted downstream of the regulating valve; and (5) an admixture produced comprises about a 3.2% by weight of glutaraldehyde, about a 0.925%

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by weight of pH adjusting agent, and a balance of water. Thus, the Examiner contends that claims 2-3, 5-6, and 9 are obvious in view of Sand et al. and Wachman et al.

As Sand et al. do not disclose the claim 1 method, which comprises the step of using a regulating valve for regulating the working pressure of the motive fluid to thereby produce a more accurate admixture than an eductor system without such regulating valve, and Wachman et al. is not relied on to disclose the use of a regulating valve, the combination is defective for not disclosing all of the claimed limitations. Reconsideration and a notice of allowance are respectfully requested.

Regarding independent claim 10, the Examiner contends that "Sand teaches a method for diluting a concentrated chemical solution with water for use in a health care facility" as recited. Although the Examiner acknowledges that "Sand fails to teach the method further comprising outputting the admixture into a holding container and applying the admixture to a surface inside a health care facility," the Examiner nonetheless asserts that such additional step "would have been obvious to one of ordinary skill in the art."

Independent claim 10 recites a method for diluting a concentrated chemical solution with water for use in a health care facility comprising the steps: providing an eductor housed in a housing; adjusting the eductor's output by adjusting a regulating valve to adjust a water supply pressure to a first pressure and adjusting a chemical inlet back pressure by selecting a metering tip having a first orifice size; hooking an inlet line connected to a container containing the concentrated chemical solution to the eductor's chemical inlet port; hooking an inlet line from a water supply source downstream of the regulating valve to the eductor's water inlet port; activating the eductor so that water flows through the water inlet port and concentrated chemical solution flows through the chemical inlet port; outputting the admixture into a holding container; and applying the admixture to a surface inside a health care facility.

Applicant respectfully disagrees that Sand et al. disclose all of the claimed limitations but for the outputting step into a holding container and using the output product on a surface inside a health care facility. As discussed above, Sand et al. only disclose a block valve 34. A block valve simply turns on or off flow. However, as water pressure fluctuates, the block valve 34 does

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not compensate for the change in pressure to thereby produce a more constant output pressure. Furthermore, Sand et al. never contemplated a pressure regulating valve as flow is instead regulated by the metering tip. Contrariwise, claim 10 recites a method for diluting a concentrated chemical solution using more than one flow regulating devices.

The Wachman et al. reference is relied on to simply disclose outputting the admixture into a holding container and applying the admixture to a surface inside a health care facility. Wachman et al. does not make up for the deficiencies of Sand et al. by disclosing a regulating valve in combination with an eductor system. Furthermore, while Wachman et al. disclose the use of sterilant for dental or medical equipment (the '323 patent, Col. 4, lines 1-5), neither Sand et al. or Wachman et al., either alone or in combination, disclose the method of diluting a concentrated sterilant solution on site in a health care facility using an eductor as claimed. Instead, Sand et al. disclose a novel eductor while Wachman et al. disclose a novel sterilant but neither disclose the method as claimed. Reconsideration and a notice of allowance are respectfully requested.

Because claims 11-13, 15-18, and 37 depend, either directly or indirectly, from claim 10, they too are allowable over Sand et al. in view of Wachman et al. for the same reasons as claim 10.

Regarding independent claim 19, the Examiner contends that Sand et al. teaches all of the elements and limitations of claim 19 except "Sand fails to teach a[n apparatus] further comprising a push button for opening a valve on the first eductor so as to permit motive source to flow through the first eductor." However, the Examiner claims that Sand teaches a device that includes a single selection control and that "it would have been obvious for one of ordinary skill in the art . . . to substitute a push button for opening a valve on the first eductor permitting a motive source to flow through the first eductor because Sand provides the motivation for a single selection control to provide the user with a simplified control means, reducing the likelihood of control or mixing error." As explained below, the rejection is traversed.

Independent claim 19 recites an apparatus for diluting a concentrate comprising: a proportioning and dispensing unit comprising at least two eductors, wherein a first eductor

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comprises a first chemical inlet port, a second chemical inlet port, a motive source inlet port, and an outlet port; a first container containing a concentrate having a container outlet port and a first hose connecting the container outlet port to the first chemical inlet port; a second container containing a pH adjusting agent having a container outlet port and a second hose connecting the container outlet port to the second chemical inlet port; a line connecting a motive source to the motive source inlet port, the line comprising a regulating valve for regulating pressure supplied by the motive source, a third hose for connecting to the outlet port of the eductor; a push button for opening a valve on the first eductor so as to permit motive source to flow through the first eductor and wherein a first metering tip is removably received in the first chemical inlet port and a second metering tip is removably received in the second chemical inlet port.

Applicant submits that Sand et al. failed to disclose several aspects of the claimed apparatus. Among other thing, claim 19 recites, in part, an apparatus for diluting a concentrate comprising a line connecting a motive source to the motive source inlet port, the line comprising a regulating valve for regulating pressure supplied by the motive source. As discussed above, Sand et al. only disclose a block valve, which does not regulate motive source pressure in the manner a regulating valve does. Hence, the device disclosed by Sand et al. cannot regulate flow in the manner which the apparatus of claim 19 does.

As Sand et al. failed to disclose all of the limitations of claim 19, Sand et al. and knowledge in the art relied on by the Examiner failed to render claim 19 obvious. Reconsideration and a notice of allowance are respectfully requested.

Because claims 21-25 and 38 depend directly from claim 19, they too are allowable over Sand et al. for the same reasons as claim 19.

In rejecting independent claim 27, the Examiner contends that Sand et al. disclose a method substantially as recited except that "Sand fails to teach that the housing is mounted in a health care facility." To make up for the shortcoming, the Examiner relied on Wachman et al. As discussed above, Sand et al. failed to disclose the method of dispensing an admixture comprising the step of connecting a water supply line to the common water inlet header of two or more eductors, the water supply line comprising a regulating valve. Furthermore, Wachman et

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al. only disclose the use of sterilant on devices, not blending sterilant using an eductor mounted in a health care facility for onsite blending. Accordingly, because Sand et al. and Wachman et al. either alone or in combination failed to disclose the method as recited, the rejection is traversed.

Because claims 28-30 and 39 depend directly from claim 27, they too are allowable over the combination of Sand et al. and Wachman et al. for the same reasons as claim 27.

§103(a) Rejection of Claims 4, 14, and 20

by Sand et al. in view of Wachman et al. and Dalhart et al.

In rejecting claims 4, 14, and 20, the Examiner contends that "Sand and Wachman teach the methods and apparatus as identified in claims 1, 10, and 19" but fail to teach a regulating valve that regulates water supply source to a water pressure of less than 50 psi. To make up for the shortcomings of the former, the Examiner relied on Dalhart et al. to disclose variation in supply pressure and that "[i]t would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the teachings of Dalhart with that of Sand and Wachman for regulating the water supply source to a water pressure less than 50 psi because this motive fluid pressure would provide the proper mixing of sterilant, diluent, and water, creating a sterilant composition appropriate for specific sterilization applications.

Applicant respectfully traverses the rejection and points out several deficiencies in the rejection. First, as discussed above, Sand et al. do not disclose a regulating valve for regulating water source pressure when the pressure fluctuates and neither Wachman et al. nor Dalhart et al. make up for the deficiency by disclosing a regulating valve. Second, the Dalhart et al. reference does not stand for the proposition cited. Instead, Dalhart et al. merely describe gravitational feed mixing assemblies and their shortcomings. In these prior art assemblies, a concentrated container is mounted upside down to feed downward to a mixing apparatus. "The action of turning the disposable [concentrated] container mechanically turns on the water and opens the orifice to allow the mixing. In another system, the user turns on water pressure and the water pressure activates a plunger mechanism to open the orifice." (Col. 1, lines 35-51). Problem

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arises when line pressure fluctuates and pushes more water through the system while the concentrated chemical is fixed by gravitational force. (Col. 1, lines 52-65). Dalhart et al. sought to overcome these shortcomings by employing venturies (i.e., eductors). "[T]he suction created by a venturi of an eductor varies with the water pressure. Consequently, the dilution ratio of an eductive dispenser varies less with water pressure than a gravity feed system" (Col. 2, lines 17-23). However, nowhere in the '318 patent did Dalhart et al. discuss the idea of using a regulating valve to regulate water pressure.

Finally, nowhere did Dalhart et al. discuss the step or concept of regulating water pressure to less than 50 psi. Dalhart et al. merely describes pressure fluctuations and the patented apparatus' ability to vary less than a comparable gravitational feed system.

Because claims 4, 14 and 20 depend from either independent claim 1, 10, or 19, and because claims 1, 10, and 19 all recite, among other things, a regulating valve for regulating the working pressure of the water supply, claims 4, 14, and 20 are patentable for at least the reasons discussed for claims 1, 10, and 19. Reconsideration and a notice of allowance are respectfully requested.

§103(a) Rejection of Claims 33-35

by Sand et al. and Wachman et al. and further in view of Stanley

The Examiner contends that Sand and Wachman teach the methods and apparatus as identified in claims 1, 10, and 19 but fail to teach the methods and apparatus further comprising hooking the water supply source to an inlet of a booster pump and hooking a pump outlet to the water inlet port of the eductor. To make up for the deficiencies, the Examiner relied on Stanley and contends that:

Stanley teaches a cleaning and sterilizing device and method that utilizes a positive pressure pump to produce positive pressure flow, which provides a greater range of pressures. Stanley further teaches that positive pressure [f]low provides both the pressure source and the fluid source at one location, simplifying

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connections and automation. Positive pressure is also safer because contaminants cannot be drawn into the device through leaks in the system.

As claims 33-35 depend from claim 1, 10, or 19, and because Sand et al., Wachman et al, and Stanley, either alone or in combination, do not disclose, among other things, a regulating valve as recited in claims 1, 10, and 19, the combination is defective and does not render claims 33-35 obvious. Furthermore, Applicant submits that Stanley is wholly inapposite. Stanley discloses a device for cleaning and sterilizing medical devices using pressure fluid. Stanley is not concerned with a product produced by the device but the device itself. Hence, Stanley did not suggest or contemplate using a pump in conjunction with an eductor for producing an admixture for use on an equipment or a device. Accordingly, the combination is defective for this additional reason.


Reconsideration and a notice of allowance are respectfully requested.

The application is thought to be in condition for allowance in view of the foregoing. Early notice thereof is respectfully solicited.

Should the Examiner finds it necessary to speak with Applicant's attorney, he is invited to speak with the undersigned at the telephone number identified below.

Respectfully submitted,

CHRISTIE, PARKER & HALE, LLP

By 
Tom H. Dao
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626/795-9900

THD/bl
Encl.: Appendix

BL IRV1C84879.1--04/11/05 9:40 AM

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